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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,818	01/16/2002	Oscar Jimenez	84167	6032

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EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 06/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/051,818

Applicant(s)

HIROMI NAMBU

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 3,4,8,9 and 14-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-7,10-13 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Examiner acknowledges receipt of IDS filed 01/16/02 and amendment A and election filed 04/14/03.

Election/Restrictions

Applicants elected Groups I and II on the basis that Group II is a method of applying the coating composition of claim 1 to a medical device. Examiner agrees with this position. Further, applicants elected heparin as the active agent but asked that claims 1-13 and 17 be examined, which means that applicants request examination of claims 3 and 8 and 4 and 9 where the active agents are antibiotic and dyes be examined with the elected species. However, this argument is not persuasive because a search for a composition comprising heparin is not necessarily a search for a composition comprising a dye or antibiotic. The claims that read on the elected species are 1, 2, 5-7, 10-13 and 17. Thus claims 1, 2, 5-7, 10-13 and 17 are examined.

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84. See attached copy Form PTO 948, Notice of Draftsperson's Patent Drawing Review. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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3. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 recites “specific dendrimers” and the specification has not described what those “specific dendrimers” are.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988)):

- 1) Nature of invention.
- 2) State of prior art.
- 3) Level of ordinary skill in the art.
- 4) Level of predictability in the art.
- 5) Amount of direction and guidance provided by the inventor.
- 6) Existence of working examples.
- 7) Quantity of experimentation needed to make or use the invention based on the content

of the disclosure.

See below:

1) Nature of the invention.

The claim is drawn to a hydrophilic coating composition comprising a mixture of colloidal aliphatic polyurethane, an aqueous dilution of PVP and specific dendrimers.

2) State of the prior art.

The prior arts do not indicate which dendrimer is specific and may be useful in the claimed invention. Applicants on page 3, line 2 of the first paragraph state “specific dendrimers”

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without identifying which polymeric molecule satisfies the structure of dendrimer that would be specific. There are many types of dendrimers and applicants in the specification, page 4, last paragraph acknowledges the existence of polyamidoamine Starburst dendrimer and does not identify said dendrimer as “specific dendrimer.”

3) Level of ordinary skill in the art.

The level of ordinary skill in the art is high. Dendrimers are a large group of polymers that has a distinct structure and architecture. Applicants’ specification does not enable the public to prepare a composition that comprises a “specific dendrimer” since there is no disclosure of what that dendrimer is.

4) Level of predictability in the art.

Applicants have no demonstration of what a specific dendrimer would be to enable one of ordinary skill in the art to predict how said special dendrimer would work in applicants claimed coating composition.

5) Amount of direction and guidance provided by the inventor.

Applicants provided no direction as to what a specific dendrimer is that would be applicable in the claimed invention.

6) Existence of working examples.

Applicants provided no working examples for specific dendrimer.

7) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The specification did not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with this claim. In particular, the specification failed to enable the skilled artisan to practice the invention without undue experimentation. The skilled artisan would have experiment with all the available dendrimers to ascertain the

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dendrimer that would work in applicants' claimed coating composition and one of skill in the art would not know which of the known dendrimers is specific.

Based on the unpredictable nature of the invention and state of the prior art and the scope of the claims, one skilled in the art could not perform the claimed process without undue experimentation; see *In re Armbruster* 185 USPQ 152 CCPA 1975.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1, 2, 5-7, 10-13 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague because it is not clear what applicants mean regarding the term "specific" as it describes dendrimers.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1, 2, 5-7, 10-13 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhong (US 5,869,127) and Mathews et al. (US 6,426,067) in view of Karimi et al. (EP 0 496 305).

Zhong discloses a method of coating a substrate with a continuous bioactive surface coating (abstract); the substrate to be coated can be a catheter (column 3, lines 65) and the bioactive agent heparin or sodium heparin (column 7, lines 49, examples 1 and 8). The coating composition also contains polyurethane; and Zhong discloses coating the substrate by dipping the substrate in the coating compositions followed by air-drying (examples 1 and 8).

Matthews discloses compositions for preparing catheters (column 12, lines 15 and 37) and the composition comprises polymer blends formed by interacting or blending two thermoplastic polymers, which may be dendrimers or dendritic polymers (column 10, line 30 and claim 9), and heparin is an example of a therapeutic agent incorporated in the polymer (column 11, line 64). Polyvinylpyrrolidone is also one of the polymers of the coating compositions (column 8, line 2)

A combined teaching of Zhong and Matthews would be a catheter coated with a composition that comprises polyurethane, heparin or sodium heparin and dendrimers or dendritic polymers or a composition that comprises polyurethane, heparin or sodium heparin and polyvinylpyrrolidone. However, the combined teaching of Zhong and Matthews failed to teach a composition that comprises polyurethane, heparin or sodium heparin and dendrimers or dendritic polymers and polyvinylpyrrolidone.

But Karimi discloses a composition that comprises a mixture of polyvinylpyrrolidone and polyurethane for coating surfaces such as catheter to make the surface lubricious such that when the medical instrument, in this case, catheter is inserted into the patient in need thereof, the lubricious surface contributes to patient comfort (page 2, lines 1-11). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to coat a

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catheter with the combined compositions of Zhong and Matthews where the coating composition comprises polyurethane, heparin or sodium heparin and dendrimers or dendritic polymers, or polyurethane, heparin or sodium heparin and polyvinylpyrrolidone. One having ordinary skill in the art would have been motivated to coat the catheter with a composition comprising polyurethane, heparin or sodium heparin and dendrimers or dendritic polymers and polyvinylpyrrolidone with the expectation that the catheter will be lubricious to contribute the comfort of the patient.

8. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara
Patent Examiner
Tech. Center 1600
June 25, 2003

